Laryngeal Injury in the Intubated ICU Patient

A Senior Honors Thesis

Presented in Partial Fulfillment of the Requirements for graduation
with research distinction in Speech and Hearing Science in the undergraduate
colleges of The Ohio State University

by

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I. Abstract

Endotracheal intubation is a regularly used life-saving process for patients brought into hospital emergency rooms. Previous research has indicated that up to 94% of patients who have undergone the endotracheal intubation procedure have sustained laryngeal injuries post extubation (Santos, 1994). However, a number of variables might affect the probability of intubation-related injury, including the size of the tube and the duration of intubation. In addition, patient-related variables such as age or gender may also play a role. The present study analyzed the type and frequency of endotracheal intubation-related injuries among patients in the Ohio State University Intensive Care Unit. In this study, 27 patients who had been intubated for longer than 24 hours underwent a videoendoscopy procedure within 48 hours of extubation. The videos were presented in a single-blind procedure to an experienced laryngeal endoscopist, such that the endoscopist was not informed regarding any details of the videos. The expert rated the degree of complications seen from the videoendoscopy procedure, indicating “yes” or “no” to the presence of vocal cord paresis/paralysis, glottic web formation, and laryngeal granuloma. The expert also rated both vocal cord erythema and laryngeal ulceration on a scale of 0-3: 0 = normal, 1 = 0-5mm, 2 = 6-10mm, and 3 = >10mm. Results indicated that all but two subjects exhibited laryngeal pathology consistent with intubation trauma. These findings did not correlate in frequency of occurrence or in severity as a function of duration of intubation, size of endotracheal tube, gender, or age. Three of the patients did require re-intubation, and all three subsequently developed laryngeal paralysis. This last finding reinforces careful selection of patients for extubation so that re-intubation may be avoided.

II. Introduction

Endotracheal intubation is one of the most common invasive procedures performed in an Intensive Care Unit, and occurs with frequent complications (Thomas, 1995). Laryngeal complications that frequently arise following extubation include, but are not limited to, vocal fold edema, erythema, ulceration, paralysis/paresis/bowing of the vocal cords, laryngeal scar, fibrosis, granuloma formation, glottic webs, and superior-laryngeal nerve paralysis (Colice, 1989). While patients frequently recover from many of these complications rapidly, it is common for some patients to experience enduring or chronic injury, such as paralysis (Cavo, 1985). Some patients must consult an Otolaryngologist following extubation as a result of certain injuries. Stridor, dysphonia, airway obstruction, and aspiration can all occur as a result of laryngeal injury (Stauffer, 1981). Furthermore, immediately following extubation, virtually every patient experiences hoarseness of voice for some period of time (Santos, 1994). For such a common procedure, the variety of potential injuries is numerous.

The purpose of this study was to identify the type and frequency of intubation-related injuries among patients in the Ohio State University Intensive Care Unit who had been intubated for at least 24 hours. The examination took place within 48 hours following extubation. The physician performing the videoendoscopic examination recorded the procedure for subsequent evaluation for examination by experts in the Otolaryngology Voice and Swallowing Disorders clinic at The Ohio State University. Upon viewing the videos, the reviewers rated the degree of complications seen from the videoendoscopy procedure.

The hypothesis was that the frequency and/or severity of laryngeal injury would increase as the size of endotracheal tube and duration of intubation also increased. Although endotracheal intubation is a life-saving procedure commonly carried out in medical intensive care units, if

laryngeal injury could be reduced simply by choosing a different endotracheal tube, anesthesiologists should be informed of this in their selection process.

III. Literature Review

The basic definition of endotracheal intubation is the insertion of a tube into the trachea via the nose or mouth for the purpose of maintaining an airway (Ambrose, 2004). It is generally performed either by anesthesiologists during surgery or by emergency room practitioners to prevent aspiration or to insure control of respiration (Ambrose, 2004). Intubation is usually done with direct laryngoscopy to visualize the placement of the tube (Batra, 2005). Given the pressing circumstances in emergency situations, there is often not much time to prepare for endotracheal intubation, and the procedure may require an emphasis on speed in restoring breathing, rather than care in preventing potential trauma during insertion (Ambrose, 2004).

There are several reasons for performing endotracheal intubation. While it can be used to provide anesthesia during surgery, there are other cases in which intubation is necessary. The airway may need to be stabilized for patients during cardiopulmonary resuscitation, coma, inhalational injury, or airway obstruction. Furthermore, head or chest injury may cause respiratory failure that may be relieved with endotracheal intubation (Ambrose, 2004).

Although there is variation, a standard endotracheal tube size for women is 7.0mm and a standard size for men is 8.0mm (Batra, 2005). Quinn (1999) stresses the importance of individualizing the size of endotracheal tube to the patient. He states that 7.0mm for women and 8.0mm for men should be the upper limits for size of the tube.

Endoscopy is a procedure by which the larynx may be viewed. The endoscope consists of a lens at the end of a scope that is inserted either orally or nasally (Karnell, 1994). A small fiber optic light extends from the lens for viewing the laryngeal area (Karnell, 1994). Videoendoscopy allows the images to be digitally recorded so that they may be saved and reviewed at a later time (Karnell, 1994). The scope is inserted above the larynx so that the glottis

may be seen. The procedure usually produces a mild discomfort (Karnell, 1994). A topical anesthetic may be applied before insertion (Karnell, 1994).

Often, endoscopy is performed at the time of intubation to minimize complications. Since endoscopy is such a basic procedure, it can is easily performed to analyze the larynx (Karnell, 1994). One limitation is that viewing the larynx does not provide the etiology of any abnormalities that may be found. Another limitation is that the scope may limit some of the vocal capabilities of the patient. Furthermore, while the visual picture may be recorded for review, there is no audio recording to accompany it. Lastly, endoscopy only provides a picture, and depending on such factors as type of scope, light source, or the angle, it may not be a very good one. Nonetheless, it is a very useful tool in laryngeal analysis (Karnell, 1994).

According to previous research, laryngeal injury occurs in up to 94% of patients who have been intubated for at least three days (Santos, 1994). The most common laryngeal injury is erythema. This red inflammation is generally not serious and nearly all cases spontaneously heal within 6 weeks (Santos, 1994). Laryngeal edema was also found to occur up to 94% in one study (Colice, 1989). Another common injury is ulceration, occurring in up to 76% of patients, also generally healing within 6 weeks (Santos, 1994). Ulcerations are caused by the endotracheal tube rubbing against the contact points in the cricoarytenoid region (Whited, 1985). A progressive soft-tissue inflammatory response in the posterior larynx is a result of ulcerations called granuloma (Whited, 1985). This is seen as a bump on one of the vocal folds. In a previous study, 44% of patients developed granuloma, 57% of which developed about 4 weeks post-extubation (Santos, 1994). In a separate study by Colice (1989), 94% of patients who were intubated at least four days showed signs of ulceration or edema. The damage was resolved within 4 weeks in 63% of the cases.

The most significant laryngeal injury noted as a result of intubation is vocal cord paralysis, paresis, or bowing (Cavo, 1985). This may be the result of peripheral nerve damage that can occur as a result of compressing the nerve between the thyroid cartilage and the inflated tube cuff (Cavo, 1985). Vocal cord immobility is noticed during endoscopy as asymmetry between the true vocal folds. Of the 97 patients in the Santos (1994) study, 8 patients were seen to have true vocal cord immobility immediately after extubation, and another 8 were seen to have true vocal cord immobility about 4 weeks after extubation. Delayed vocal cord immobility was seen only in patients who had been intubated with a size 8.0mm endotracheal tube. Vocal cord immobility can lead to severe dysphonia, dysphagia, aspiration, and potential airway obstruction (Santos, 1994). True vocal cord immobility is usually temporary (Santos, 1994).

Previous studies have shed some light on laryngeal damage caused during intubation. Kastanos (1983) found that severe respiratory failure, endotracheal tube cuff pressure, and secretion infection were statistically correlated with tracheal injury. In this study, 12 patients showed laryngeal injury post extubation. Of these 12, all but 3 had shown resolution within three months.

Gaynor (1988) studied the effects of gastroesophageal reflux in the larynx during intubation. 40% of the patients in this study who were not receiving antacid therapy were found to have gastroesophageal reflux present in the larynx. Tests on rabbits and canines have indicated that exposure to gastric juices may lead to marked inflammation, necrosis, and reduced mucociliary flow. This study stresses the importance of antacid therapy during intubation to reduce further potential damage to the larynx.

Mandøe (1992) conducted a study of sore throat following intubation. This study tested the effectiveness of a new brand (Brandt Anestheisa Tube) of endotracheal tube that reduces the

increase of cuff pressure due to diffusion of nitrous oxide. Following interviews with the extubated patients, the new tube was deemed effective in reducing sore throat. This may suggest that increased intracuff pressure can lead to further complications.

Thomas (1995) conducted a similar long term study of post-intubation patients. In this study, long term laryngeal complications were linked to patients with seizures, patients with head trauma, and deeper insertion of the endotracheal tube.

Ellis (1996) conducted a study in which patients were examined via endoscopy prior to being intubated. It was found that patients who showed some signs of laryngeal pathology prior to intubation were at a higher risk for complications post-extubation than those who showed no signs of pathology prior to intubation. This study also found that patients who admitted to a recent history of smoking were more likely to show signs of abnormalities following extubation.

Conlan (2000) weighed the costs and benefits of tracheostomy as compared to pronlonged endotracheal intubation in the ICU. In this analysis, it was determined that most patients requiring mechanical ventilation for more than 2 weeks would benefit more from a tracheostomy than prolonged intubation. Some of the benefits of tracheostomy outlined by Conlan include avoidance of direct laryngeal injury, improved patient comfort, permissibility of speech, enhanced patient mobility, oral feeding, and psychological benefits, et al. Conlan highlights the importance of proper timing for the switch from the temporary endotracheal intubation to the tracheostomy in order to reduce complications. At this time, there are no set guidelines as to when this switch should be made.

This current study focused on the adult population, looking at patients who had been intubated for at least 24 hours. The goal was to examine patterns of laryngeal injury arising among these patients. It is hypothesized that prolonged intubation will lead to a higher incidence

and severity of laryngeal injury. It is also hypothesized that larger endotracheal tube size will also be associated with higher incidence and severity of laryngeal injury. The study also analyzed such factors as the number of re-intubations, presence of oro-gastric and naso-gastric tubes, tracheostomy, and gastroesophageal reflux medication usage.

IV. Methods

Participants in this study included 16 men, ages 43-81, and 11 women, ages 45-84. Participants were recruited from the Ohio State University intensive care unit after having been intubated for at least 24 hours. The duration of intubation amongst the patients ranged from 1 day to 22 days. The reason for intubation varied among patients. (Appendix #1) The endotracheal tubes used in these intubations were made of silastic material, and varied in diameter from 7.0mm-8.0mm. Data on who performed the intubation was not collected. Recruitment was done by Brad deSilva, M.D., a 5th year resident in the Department of Otolaryngology at the Ohio State University Medical School. Dr. deSilva discussed the nature of the study with the participants and/or their family. The investigator received written consent from the participants. (Appendix #2) Demographic data, including patient age, gender, principal diagnosis, duration of intubation, number of re-intubations, size of endotracheal tube, whether patient had undergone tracheostomy, presence of oro-gastric or naso gastric tube, and use of proton pump inhibitors were collected. The study received institutional I.R.B. approval. (Protocol #2007H0065)

Following consent, the patients underwent a bedside laryngoscopic procedure within 48 hours of extubation. Dr. deSilva conducted the exams, which typically lasted about 90 seconds. The mean time that the glottis was visible was about 45 seconds. No patient preparation was necessary. A 4% Lidocaine topical anesthesia was diluted 50/50 with Afrin solution. The procedure used an Olympus 4mm flexible fiberoptic nasopharyngoscope. A Richard Wolf 5502 Endocam camera was used along with a Sony SVO- 1520 video cassette recorder. During the examination, patients were asked to vocalize /i/. There was no cost to the participant for

undergoing the laryngoscopy procedure. After the examination, the participant was either dismissed or referred for follow-up examination and/or treatment if pathologies were severe.

These procedures were videotaped and presented to Michael Trudeau, Ph.D., a faculty member of the Department of Otolaryngology and licensed speech-language pathologist. Dr. Trudeau received both a M.A. and Ph.D. in Speech-Language Pathology from Ohio State University. He has been a practicing speech-language pathologist since 1978, and has been on the faculty at Ohio State since 1983. Dr. Trudeau was not given the patient's identity or demographic information. At the time of expert review, he was presented with a random video, via VCR of one of the procedures. Dr. Trudeau was asked to review each video as long as needed, as well as to adjust the lighting in the room, to accurately answer the questions on each data collection sheet. Pausing and rewinding the video were allowed. Mr. Olszewski was present with the Dr. Trudeau at the time of review and recorded the responses on data collection sheets. (Appendix #3)

Dr. Trudeau was asked to rate presence of vocal fold erythema. This was rated on a scale of 0-3, where 0 = normal, 1 = 0-5mm, 2 = 6-10mm, and 3 = >10mm of erythema. He was also asked to rate laryngeal ulceration, according to the same 0-3 scale. Then he was asked to respond yes or no to each for the presence of vocal fold paresis/paralysis, laryngeal granuloma, and glottic web formation. The information collected was kept accessible only to those investigators working on this study.

V. Results

Of the 27 patients who took part in this study, only 2 were found to have no signs of laryngeal pathologies post-extubation. One was a male intubated for 5 days with an 8.0mm ET diameter. The second was a female intubated for one day with a 7.0mm ET diameter. In addition, one male intubated for 8 days with an 8.0mm ET diameter was viewed to have no pathologies other than paralysis which was noted prior to intubation. An additional three patients exhibited only one pathology post-extubation. Two of these were females (size 7.0mm and 7.5mm ET) who exhibited >10mm erythema, but nothing else. The third was a male (size 7.5mm ET) who showed 0-5mm ulceration. In the overall sample, the total number of pathologies seen in each patient ranged from 0-3.

Overall in this sample, 7 of the 16 males and 3 of the 11 females had some form of paralysis/paresis/bowing at the time of examination. Two patients, both male, exhibited glottic web formation. 3 males and 6 females showed granuloma. Ulceration and erythema were rated on scales. Ulceration greater than 10mm. was found in only one of the 27 patients. This female was intubated 11 days with a size 8.0mm ET. However, ulceration between 5-10mm was found in 2 males and 2 females, and 0-5mm was found in 4 males and 1 female. Erythema greater than 10mm was found in 7 males and 7 females. 5-10mm of erythema was found in 3 patients, all male. 0-5mm was found in only one patient (female). The mean number of pathologies for each patient was 1.81. All patients who were found to have granuloma were found to have either one or two other pathologies present simultaneously. Similarly, all patients who were found to have true vocal cord paralysis (except the patient who had identified paralysis prior to intubation) were found to have one or two other pathologies present simultaneously. However, there did not seem to be an association between granuloma and paralysis.

Pathology	Frequency	Gender
No Pathology	2	1 M:1 F
Erythema	18	10 M:8F
Ulceration	10	6M:4F
Paralysis	10	7M:3F
Granuloma	9	3M:6F
Glottic Web	2	2M

Table 1. Frequency of laryngeal pathology post intubation as a function of gender.

It should be noted that no association was found between the age of patients and duration of intubation. Results were plotted on a spreadsheet, and a Pearson's product moment correlation coefficients were calculated. The correlation coefficient for age (in years) and number of pathologies was -0.148. The correlation coefficient for number of days of intubation and number of pathologies was -0.025. Neither of these coefficients is significant. A chi-squared test was performed with number of injuries as a function of gender: $\chi^2 = 0.09$, $\alpha = 0.050$. This was not significant. Another chi-squared test looked for correlation between serious injuries (i.e. granuloma and/or paralysis) and duration of intubation. Patients were divided into two groups, those who were intubated five days or less, and those intubated six days or longer. This test found $\chi^2 = 1.29$, $\alpha = 0.050$. This was not significant. Nevertheless, there were twice as many patients exhibiting serious injuries in the ≥ 6 days group (10) than there were in the ≤ 5 days group (5). There was only one more patient in the ≥ 6 days group. Small sample size may have been a reason no correlation was found between duration of intubation and presence of serious pathology.

Only one patient had neither oro-gastric or naso-gastric tubes. This patient was a female intubated for 14 days with a size 8.0mm ET. Post-extubation, she showed paralysis and granuloma. However, the video was too dark to judge erythema and ulceration. Two of the patients in this study underwent tracheostomy. In both cases, supraglottic edema and secretions were copious. During review, the judge was unable to comment on any other pathology due to the quantity of the secretions.

Of the 27 patients in this study, 3 were not taking medication to control acid reflux. All three of these patients experienced some gastroesophageal reflux related injury. One patient intubated for 9 days experienced only mild ulceration, nothing else. A second was intubated for 2 days and showed >10mm erythema, paralysis, and granuloma. The third patient was intubated for 10 days and also showed >10mm erythema, as well as glottic web formation.

As far as ET size is concerned, no direct relationships were found. A chi-squared test was performed with number of pathologies as a function of ET diameter. $\chi^2 = 0.816$. This is not significant with $\alpha = 0.050$. One male was intubated with a 7.0mm ET and exhibited 3 pathologies post-extubation. 2 males had 7.5mm ETs. One showed 2 pathologies, the other showed 3. However, of the 13 males intubated with 8.0mm ETs, the number of pathologies ranged from 0-3. Females with a 7.0mm ET had anywhere from 0-3 pathologies. All of the females intubated with a 7.5mm ET exhibited one or more pathologies, and females intubated with an 8.0mm ET showed 2 or more pathologies.

VI. Discussion

The results of this study show that most endotracheal intubations result in laryngeal injury. Results found no direct relationship between duration of intubation, age, size of ET used, or use of gastroesophageal reflux medication and laryngeal pathology. This could be due to a number of factors, including small sample size. Other studies of this topic had anywhere from 19 to 150 patients. It should be noted that in studies with larger numbers of participants, data collection occurred over many months or years. Data in this study was collected between October 10, 2007 and April 9, 2008. An association was found, however, between more severe injuries (i.e. granuloma and paralysis) and number of pathologies. High ratings of erythema were generally found with these pathologies. The implications of this study suggest that further research is warranted.

Initially, the design of this study included return for a follow up examination for all participants every two weeks for a total of three examinations. However, given the location of the University Medical center as compared to neighboring medical centers, patients who live a distance away were not motivated to return for such a short examination. Also, some of the patients remained very ill or expired shortly afterwards. Follow up examinations would have provided more insight on the duration and severity of some of the pathologies. It would also provide a time frame of how long it takes for patients to recover, and of degree of recovery.

Another design factor which may have added to the reliability of this study would be to have a second expert judging the videos. By having two judges, inter-rater reliability can be tested. The results in this study are based on the judgments of one expert.

One way to look for a correlation might be to gather more data from each individual. ET size may not have shown a correlation in this study because there is no indication of how each

ET size was chosen for the individual. By measuring the size of the glottis, the percentage of space the tube takes up can be calculated. The patients in this study who experienced more pathologies than other patients may have been intubated with a tube size not well suited to their glottis.

Also, previous history of laryngeal pathologies was not noted. The number of initial diagnoses in this study was too vast to find any correlation with a limited sample. However, as pointed out in Ellis (1996), patients who have some form of laryngeal pathology are more likely to experience pathology post extubation. Only one patient in this study was noted to have pathology prior to intubation and that was true vocal cord paralysis. This individual was intubated for 8 days, and post-extubation the only pathology noted was the paralysis. In addition to previous history of intubation, previous smoking history could add another piece to the puzzle.

It might also be beneficial to collect information on who performed each intubation, and the location it was performed. It could be hypothesized that someone experienced would perform the procedure more delicately than someone lacking experience. Furthermore, it is hypothesized that a clinical setting would also be more conducive to a more carefully placed tube as opposed to an emergency field setting. Reasoning for why certain patients were re-intubated could also be gathered. In this study, three of the 27 patients were re-intubated. All three of these patients exhibited vocal cord paralysis and greater than 5mm of erythema post-extubation.

As far as looking for correlations between gastroesophageal reflux and laryngeal injury, the only information collected in this study was about the medications. It was not noted whether the patients had any history of gastroesophageal reflux disorder. In this study, three of the 27 patients were taking no form of medication to control gastroesophageal reflux. It is not noted why they were not but others were. All three of these patients exhibited some form of

gastroesophageal reflux related pathology upon review. Another study measuring the amount of gastroesophageal reflux in patients during intubation might be revealing, although very difficult to perform.

One major finding of this study is that laryngeal injury in the intubated ICU patient may not be as clear-cut as previous studies show. It is not as simple as saying that patients with a size 8.0mm ET are at higher risk for injury than patients with a size 7.0 ET. It is also not enough to pick one size for each gender. One can infer that a multitude of individual factors play a role in causing a patient to be at-risk for injury. This study indicates that two areas that should definitely be considered further are gastroesophageal reflux management and re-intubation. Tube selection size for each patient should be done on a case-by-case basis.

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Appendix 1
Table of Results by Patient

Appendix 1: Table of sample demographics and observed laryngeal pathologies

Subject	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**
Gender	M	M	F	M	F	M	M	M	M
Age	43	52	48	47	45	67	60	77	57
Principal Diagnosis	COPD Exacerbation	Cervical Stenosis/Resp	Asthma	Aspiration,	Suicide Attempt/ OD	Lung Ca, TVC	PE, Thymic Cancer	Osteomyelitis w/	CVA
Duration of	13	5	1	5	1	8	1	6	2
Number of Re-	1	0	0	0	0	0	0	1	0
Tracheostomy (Y/N)	N	N	N	N	N	N	N	N	N
Size of	7.5	8	8	8	7	8	8	8	7
OG/NG	NG	NG	Y	OG	Y	NG	NG	NG	NG
PPI	Nexium	Nexium	Nexium	N Pepcid	Y-Not specified	Nexium	Nexium	Nexium	None
Erythema	3	0	3	2	1	0	3	3	3
Paresis/Paralysis	Y	N	N	N	Y	Y	N	Y	Y
Glottic Web	N	N	N	N	N	N	Y	N	N
Ulceration	0	0	1	2	0	0	1	0	0
Granuloma	N	N	Y	N	N	N	N	Y	Y
Subject	**10**	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18**
Gender	M	F	F	F	M	M	F	M	M
Age	82	67	67	84	71	81	74	51	60
Principal Diagnosis	CO Suicide	Mediastinal LAD/Resp	Cardiomyopathy	Hypertensive	Encephalitis/Resp F	Intracranial	Renal Failure	Epidural	Resp Failure
Duration of	1	3	11	1	9	13	1	8	22
Number of Re-	0	0	0	0	0	1	0	0	0
Tracheostomy (Y/N)	N	N	N	N	N	N	N	Y	Y
Size of	8	7	8	7	8	8	7	8	8
OG/NG	Y	Y	NG	NG	OG	OG	NG	NG	OG
PPI	Nexium	Nexium	Nexium	N Pepcid	N	N Pepcid	N Pepcid	N Pepcid	Nexium
Erythema	2	3	0	3	0	2	0	supraglottic edema	supraglottic
Paresis/Paralysis	N	Y	N	N	N	Y	N	secretions too	too severe to
Glottic Web	N	N	N	N	N	Unsure	N	to comment	noted
Ulceration	1	0	3	0	1	0	0		OG tube
Granuloma	N	N	Y	N	N	N	N		
Subject	**19**	**20**	**21**	**22**	**23**	**24**	**25**	**26**	**27**
Gender	F	F	M	F	F	M	M	M	F
Age	69	48	60	70	69	72	46	69	57
Principal Diagnosis	Tracheal Stenosis	Ascites/Resp F	Pneumonia	Not Noted	Resp Failure	Pneumonia	Intracranial	ARF, Sepsis	Meningitis
Duration of	6	4	1	14	7	17	10	13	7
Number of Re-	0	0	0	0	0	0	0	0	0
Tracheostomy (Y/N)	N	N	N	Not Noted	N	N	N	N	N
Size of	7	7.5	7.5	8	7	8	8	8	7.5
OG/NG	OG	NG	NG	N	OG	OG	OG	NG	NG
PPI	N Pepcid	Y Nexium	N Pepcid	Y	Nexium	Nexium	N	Nexium	N Pepcid
Erythema	3	3	3	Too Dark To Note	3	Too Dark To	3	3	3
Paresis/Paralysis	N	N	Y	Y	N	Y	N	N	N
Glottic Web	N	N	N	N	N	N	Y	N	N
Ulceration	0	0	0	Too Dark To Note	2	1	0	2	2
Granuloma	Y	N	Y	Y	Y	N	N	N	Y

Appendix 2
Consent Form

The Ohio State University Consent to Participate in Research

Study Title: **Laryngeal Injuries in the Intubated ICU Patient**

Principal Investigator: **Lowell Arick Forrest, MD**

Sponsor: Ohio State University Medical Center

- **This is a consent form for research participation.** It contains important information about this study and what to expect if you decide to participate. Please consider the information carefully. Feel free to discuss the study with your friends and family and to ask questions before making your decision whether or not to participate.
- **Your participation is voluntary.** You may refuse to participate in this study. If you decide to take part in the study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your usual benefits. Your decision will not affect your future relationship with The Ohio State University. If you are a student or employee at Ohio State, your decision will not affect your grades or employment status.
- **You may or may not benefit as a result of participating in this study.** Also, as explained below, your participation may result in unintended or harmful effects for you that may be minor or may be serious depending on the nature of the research.
- **You will be provided with any new information that develops during the study that may affect your decision whether or not to continue to participate.** If you decide to participate, you will be asked to sign this form and will receive a copy of the form. You are being asked to consider participating in this study for the reasons explained below.

1. Why is this study being done?

To study the effects of having a breathing tube in place and any injury it may cause to the vocal cords and voice box in an intensive care unit patient.

2. How many people will take part in this study?

100 patients

3. What will happen if I take part in this study?

The participant is consenting to having an exam of the larynx (voice box) done by video recording images obtained from a flexible telescope passed into the nose to the back of the throat. The nose is sprayed with Afrin (decongestant) and Lidocaine (anesthetic) to make the exam comfortable. The exam will take 1-2 minutes and be video recorded. The exam is a basic

part of an Ear, Nose, and Throat Physician's routine physical exam. The risks are mild nasal discomfort and potential allergy to the medications administered to the nose.

4. How long will I be in the study?

A total of three exams will be performed. The first is within 48 hours of the breathing tube being removed. The following two exams are done at 2 weeks and 4 weeks after the first exam. If there is a sign of vocal cord or voice box abnormality on the exam, then this may require further follow-up with an Ear, Nose, and Throat physician.

5. Can I stop being in the study?

Yes.

You may leave the study at any time. If you decide to stop participating in the study, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled. Your decision will not affect your future relationship with The Ohio State University.

6. What risks, side effects or discomforts can I expect from being in the study?

Mild discomfort in the nose from having an exam of the voice box performed. There is the possibility of allergic reaction to the administered medications Afrin (decongestant) and Lidocaine (anesthetic).

7. What benefits can I expect from being in the study?

Increasing the knowledge of the effects on the vocal cords and voice box after having a breathing tube in place and allowing early detection of vocal cord injury in order to prevent long term injury.

8. What other choices do I have if I do not take part in the study?

You may choose not to participate without penalty or loss of benefits to which you are otherwise entitled.

9. Will my study-related information be kept confidential?

Efforts will be made to keep your study-related information confidential. However, there may be circumstances where this information must be released. For example, personal information regarding your participation in this study may be disclosed if required by state law. Also, your records may be reviewed by the following groups (as applicable to the research):

- Office for Human Research Protections or other federal, state, or international regulatory agencies;
- U.S. Food and Drug Administration;

- The Ohio State University Institutional Review Board or Office of Responsible Research Practices;
- The sponsor supporting the study, their agents or study monitors; and
- Your insurance company (if charges are billed to insurance).

If the study involves the use of your protected health information, you may also be asked to sign a separate Health Insurance Portability and Accountability Act (HIPAA) research authorization form.

10. What are the costs of taking part in this study?

There are no inherent costs to the participant. The examinations and review will be free of charge. The study may require follow-up exams at the Ohio State University Ear, Nose, and Throat clinic after discharge from the hospital in which the participant would have to pay for travel and parking. Any new conditions discovered during the examinations may require further medical care and follow-up. Medical care rendered following the three examinations may be billed to the patient and/or insurance.

11. Will I be paid for taking part in this study?

No.

12. What happens if I am injured because I took part in this study?

If you suffer an injury from participating in this study, you should notify the researcher or study doctor immediately, who will determine if you should obtain medical treatment at The Ohio State University Medical Center.

The cost for this treatment will be billed to you or your medical or hospital insurance. The Ohio State University has no funds set aside for the payment of health care expenses for this study.

13. What are my rights if I take part in this study?

If you choose to participate in the study, you may discontinue participation at any time without penalty or loss of benefits. By signing this form, you do not give up any personal legal rights you may have as a participant in this study.

You will be provided with any new information that develops during the course of the research that may affect your decision whether or not to continue participation in the study.

You may refuse to participate in this study without penalty or loss of benefits to which you are otherwise entitled.

An Institutional Review Board responsible for human subjects research at The Ohio State University reviewed this research project and found it to be acceptable, according to applicable state and federal regulations and University policies designed to protect the rights and welfare of participants in research.

14. Who can answer my questions about the study?

For questions, concerns, or complaints about the study you may contact**:**
Brad deSilva, MD at 614 293-8077 or 614 293-8000._____.

For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact Ms. Sandra Meadows in the Office of Responsible Research Practices at 1-800-678-6251.

If you are injured as a result of participating in this study or for questions about a study-related injury, you may contact **:**
Brad deSilva, MD at 614 293-8077 or 614 293-8000. _____.

Signing the consent form

I have read (or someone has read to me) this form and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to participate in this study.

I am not giving up any legal rights by signing this form. I will be given a copy of this form**.**

Printed name of subject	**Signature of subject**
	AM/PM
	Date and time
Printed name of person authorized to consent for subject (when applicable)	**Signature of person authorized to consent for subject (when applicable)**
	AM/PM
Relationship to the subject	**Date and time**

Investigator/Research Staff

I have explained the research to the participant or his/her representative before requesting the signature(s) above. There are no blanks in this document. A copy of this form has been given to the participant or his/her representative.

Printed name of person obtaining consent	**Signature of person obtaining consent**
	AM/PM
	Date and time

Witness(es) - *May be left blank if not required by the IRB*

Printed name of witness	**Signature of witness**
	AM/PM
	Date and time
Printed name of witness	**Signature of witness**
	AM/PM
	Date and time

Appendix 3
Data Collection Sheet

Laryngeal Injuries in the Intubated ICU Patient
Data Collection Sheet

Name: MRN:

Age: Gender: M / F Principal Diagnosis:

Date of Intubation: Date of Extubation: Duration of Intubation:
Number of Re-intubations: Tracheostomy Performed: Y / N
Size of Endotracheal Tube: Presence of OG/NG tube: Y / N
Use of Proton Pump Inhibitor: Y / N

Exams:
Date:
Vocal Cord Erythema: 0 1 2 3 Laryngeal Ulceration: 0 1 2 3
Vocal Cord Paresis/Paralysis: Y / N Laryngeal Granuloma: Y / N
Glottic Web Formation: Y / N

Date:
Vocal Cord Erythema: 0 1 2 3 Laryngeal Ulceration: 0 1 2 3
Vocal Cord Paresis/Paralysis: Y / N Laryngeal Granuloma: Y / N
Glottic Web Formation: Y / N

Date:
Vocal Cord Erythema: 0 1 2 3 Laryngeal Ulceration: 0 1 2 3
Vocal Cord Paresis/Paralysis: Y / N Laryngeal Granuloma: Y / N
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Vocal Cord Paresis/Paralysis: Y / N Laryngeal Granuloma: Y / N
Glottic Web Formation: Y / N

Date:
Vocal Cord Erythema: 0 1 2 3 Laryngeal Ulceration: 0 1 2 3
Vocal Cord Paresis/Paralysis: Y / N Laryngeal Granuloma: Y / N
Glottic Web Formation: Y / N

Scale: 0=normal, 1 = 0-5 mm, 2 = 5-10mm, 3 = >10 mm erythema/ulceration.